National Enforcement Investigations Center

NEIC

NEICVP1359E01

NEIC CIVIL INVESTIGATION REPORT
Clean Air Act Inspection
Guidant Puerto Rico, B.V.
(dba Boston Scientific Puerto Rico)

Dorado, Puerto Rico

Inspection Date :
December 3, 2019

ARMANDO BUSTAMANTE

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INVESTIGATION OVERVIEW

PROJECT OBJECTIVE

At the request of U.S. Environmental Protection Agency (EPA) Region 2, EPA National Enforcement Investigation Center (NEIC) inspectors accompanied Alex Rivera of EPA Region 2, Caribbean Environmental Protection Division (CEPD), during a continuation of a Clean Air Act (CAA) compliance inspection of Guidant Puerto Rico, B.V. (dba Boston Scientific Puerto Rico) in Dorado, Puerto Rico (Boston Scientific) on December 3, 2019. Mr. Rivera previously conducted an inspection of the facility on September 5-6, 2019. The scope of the inspection was to determine Boston Scientific's compliance with 40 Code of Federal Regulations (CFR) Part 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities. The scope of NEIC's involvement was to assist EPA Region 2 in determining compliance with 40 CFR Part 63 Subpart O, observe and evaluate site conditions and operation of control devices, and conduct fugitive emission monitoring. Inspection credentials were presented to Iliette Frontera, Boston Scientific vice president (VP) of operations.

The project team members are listed in **Table 1**.

Table 1. PROJECT TEAM MEMBERS

Team Member	Organization	Project Role
Armando Bustamante	NEIC	Project manager (PM)
Matthew Schneider	NEIC	Field team member
Alex Rivera	EPA Region 2 CEPD	Field team member

FACILITY CONTACT INFORMATION

Table 2 lists the primary facility contacts. Mr. Ariel Gonzalez, environmental, health, and safety (EHS) manager, was attending a conference in Ireland and was not present for the inspection

Table 2. FACILITY CONTACT INFORMATION

Name, Title	Email Address
Ariel Gonzalez, EHS Manager	ariel.gonzalez@bsci.com
Iliete Frontera, VP Operations	iliette.fronteraagenjo@bsci.com

FACILITY OVERVIEW

Boston Scientific operates as a specialized medical device manufacturing facility. The facility manufactures leads that are used in cardiac rhythm and neuromodulation control management devices. Prior to use, the leads must be sterilized, and Boston Scientific accomplishes sterilization of the leads by exposure to ethylene oxide (EtO) in its on-site sterilization facility.

Boston Scientific currently operates two sterilization chambers and is in the process of validating a third chamber. Each of the chambers currently being used has a capacity of 100 cubic feet; the third chamber will provide an additional 200 cubic feet of capacity.

Chamber validation consists of three sterilization cycles of a random sample to determine operating conditions to meet the limit for residual EtO. The EtO residual limit is set by the International Organization for Standardization (ISO) standard 10993-7 and is a maximum EtO dose of 4 milligrams (mg) in the first 24 hours. After validation, the chamber can be placed into use. Boston Scientific conducts chamber validation yearly.

Leads are sterilized in primary Tyvek packaging instead of the final packaging. This practice minimizes the amount of EtO required for proper sterilization and exposure time and does not require aeration after the sterilization process is complete.

The sterilization cycle can range from 8 to 10 hours, depending on the type of device being sterilized. The cycle consists of conditioning, sterilization, and degassing. Once the sterilization cycle begins, the chamber door is locked, and the chamber room is placed under negative pressure. The conditioning phase prepares the devices for sterilization by increasing the temperature and humidity in the chamber. Sterilization occurs with the injection of EtO gas and an exposure time ranging from 15 to 30 minutes. After the exposure time is complete, the chamber is degassed to a catalytic oxidizer. The EtO concentration in the chamber is monitored by a gas chromatograph instrument. The cycle is complete, and the chamber door can be opened, when the chamber EtO concentration is less than 0.5 parts per million. After the cycle is complete, the sterilized devices are placed into final packaging for distribution.

Boston Scientific conducted performance testing on the catalytic oxidizer when the third chamber was installed in 2019. The performance test was conducted with all three chambers running to ensure that the control device could handle the additional load, and the result showed a 99.96 percent EtO removal efficiency. Boston scientific monitors and records the oxidation temperature at the outlet to the catalyst bed continuously. The oxidizer catalyst was last changed in 2015 and is scheduled to be changed again in 2020. Boston Scientific uses greater than 1 ton but less than 10 tons per year of EtO. Boston Scientific had used approximately 7,800 pounds of EtO through November 2019.

FIELD ACTIVITIES SUMMARY

The EPA field team conducted the following activities as part of the on-site inspection:

- Interviewed facility personnel to obtain a thorough understanding of the sterilization process
- Conducted a site tour that included all operations at the facility
- Inspected the sterilization chambers, closed vent systems, and control devices
- Conducted fugitive emissions monitoring using EPA Method 21

Determining compliance with the facility's air operating permit was outside the scope of the NEIC inspection.

Measurement Activities

All environmental measurement activities were performed in accordance with the NEIC quality system. All field measurements described in this report are within the scope of NEIC's ISO/IEC 17025 accreditation issued by the ANSI National Accreditation Board (certificate No. AT-1646).

Table 3 summarizes field measurement activity.

Table 3. FIELD MEASUREMENTS PERFORMED

Location Description	Date	Method and/or Procedure and Equipment	Measurer Name
Closed vent system and the EtO storage and vaporization system	December 3, 2019	**Method:** EPA Method 21: Determination of Volatile Organic Compound Leaks **NEIC Procedure:** *Toxic Vapor Analyzer (TVA)*, NEICPROC/00-016 **Equipment:** TVA2020, NEIC ID No.: B24310	Armando Bustamante

Valves, pumps, connections, and other equipment associated with the sterilization chambers could not be monitored because the chamber door was locked, and the equipment was inaccessible during the sterilization cycle.